General Protocol Review Checklist
(For Use of CDC IRB Members)

CDC Protocol # _____

CDC IRB: _____

Reviewer: _____

Date: _____

Title 45, Part 46, Code of Federal Regulations (45 CFR 46), outlines the basic Department of Health and Human Services policy for the protection of human subjects involved in any research activities conducted by or funded by CDC. Section 111 of 45 CFR 46 (§46.111) outlines seven criteria that must be satisfied for IRB approval of research covered by this policy. The purpose of this checklist is to aid in the evaluation of the documentation accompanying requests for protocol approval at CDC.

First, please evaluate the level of risk involved in the proposed study. The federal regulations designate risk as either "minimal or not greater than minimal" risk or that which is "greater than minimal." The definition of "minimal risk" stated in §46.102(i) is:

> Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Level of risk for this proposed study:

_____

(please insert either "minimal" or "greater than minimal")

Next, please evaluate the proposed study based on the following seven criteria outlined in the federal regulations. Designate in the last block for each of the seven criteria either **N** (not adequately addressed), **Y** (adequately addressed), **AIN** (additional information needed to assess), or **NA** (not applicable).

Criteria	Determination/Notes
1. Are the risks to participants minimized through: (a) procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (b) when appropriate, through procedures already being performed on the subjects for diagnostic or treatment purposes?	

2. Are risks to subjects reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may reasonably be expected to result? (IRBs should consider only those risks and benefits that may result from the research. IRBs should not consider possible long-range effects of applying knowledge gained in the research.)	
3. Is the selection of subjects equitable? (IRBs should consider the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations.*)	
4. Will informed consent be sought from each prospective subject or the subject's legally authorized representative in accordance with and to the extent required by 45 CFR 46.116? (see Informed Consent Checklist)	
5. Will informed consent be appropriately documented in accordance with and to the extent required by 45 CFR 46.117?	
6. When appropriate, will the research plan make adequate provision for monitoring the data collected to ensure the safety of subjects?	
7. When appropriate, are there adequate provisions to protect the privacy of individuals and to maintain the confidentiality of data?	

*The federal regulations define vulnerable populations as subjects who are likely to be vulnerable to coercion or undue influences such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The regulations address additional safeguards necessary to protect the interests of children in subpart D of 45 CFR 46, of prisoners in subpart C, and of pregnant women in subpart B; however, the regulations do not provide specific guidance to address additional safeguards for mentally disabled persons or for economically or educationally disadvantaged persons.